Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

DISCUSSION QUESTIONS
General and Plastic Surgery Devices Panel
November 18, 2010
PMA: PMA P090012, MelaFind

1. Are there sufficient data to evaluate the risk/benefit trade-off for MelaFind use versus "standard" lesion management in terms of number of unnecessary biopsies (false positives) to potentially find melanomas (true positives)? Has the introduction of MelaFind to a clinical setting, as per the sponsor's proposed Indications for Use, been properly evaluated?
2. Do the presented data support MelaFind use by a physician or other healthcare professional for all atypical lesions (has at least 1 characteristic of ABCDEPRU)?
3. Has the sponsor provided adequate data to validate whether or not physicians or health care providers who are not dermatologists or trained in melanoma detection can safely use MelaFind to identify atypical lesions? Specifically, please comment on the risk of not referring forward or not biopsying melanomas because of a MelaFind false negative result or non evaluable reading (device failure) relative to the benefits of having MelaFind as an aid in assessing atypical lesions.
4. Are the data presented in Protocol 20061 on the 97 lesions with one or no characteristics of the ABCDEPRU criteria out of the 1632 Eligible and Evaluable lesions sufficient to establish MelaFind performance on all atypical lesions?
5. Please comment on the impact of the un-evaluable lesions, as a result of device failure, on the performance of the MelaFind for patients with atypical lesions in a clinical setting.
6. Please comment on the need for a post-approval study.

   If a PAS is recommended, please briefly discuss:
   - the objectives and hypotheses
   - clinical endpoints
   - study size
   - comparison group(s)
   - duration of follow-up for study subjects
   - other specific issues that you would like to be addressed in the PAS